

Remarks

Claims 1-24 are pending. Claims 5, 7, 13, 14 and 17-24 are withdrawn from consideration. Claims 1-4, 6, 8-12, 15 and 16 are rejected.

Information Disclosure Statement

Applicant submitted an Information Disclosure Statement (IDS) mailed on July 30, 2003. In the Office Action mailed on January 18, 2007, the Examiner indicated that he could not locate the Form PTO-1449 filed with the IDS so that he could sign off the references filed in the IDS. Applicant re-submitted a copy of the PTO-1449 as filed on July 30, 2003 in the response to Office Action submitted on March 19, 2007. However, the Office Action mailed on June 7, 2007 does not include the initialed Form PTO-1449.

Applicant again respectfully requests the Examiner to return the Form PTO-1449 where the references are initialed or signed off.

Claim Rejections – 35 U.S.C. § 103(a)

Claims 1-4, 6, 8-12, 15 and 16 have been rejected under 35 U.S.C. § 103(a) as being obvious over EP 0 970 711 A2 by Ethicon (“Ethicon”).

Claim 1 defines a coating for an implantable medical device comprising a first region having a drug and a second region on the top of the first region having a polymer. The polymer has a glass transition temperature between 35 °C and about 50 °C and contains less than about 1 mass % of water.

Ethicon describes a process of forming a coating on a stent. The coating can include a non-acrylic polymer such as vinyl halides, polystyrenes or polyoxymethylenes. However, Ethicon does describe or teach, among other features, using a polymer containing less than about 1 mass % of water.

In the Office Action mailed on June 7, 2007, the Examiner appears to have ignored the water content entirely as a limitation of the coating defined by claim 1. This is clearly improper. As Applicant pointed out in the response to Office Action filed on March 19, 2007, the water content as defined by claim 1 is an important feature of the coating defined by claim 1. For example, water is a plasticizer of polymer, and the content of water can affect the glass transition temperature of a polymer (see, e.g., E. Laredo, M.C. Hernandez, The Bulletin of the American Physical Society, Conference Abstract, B31.07, March 17, 1997). In addition, moisture content has a marked effect on tensile properties of polymer compositions (see, e.g., J.L. Willett and W.M. Doan, Polymer, 43(16):4413-4420 (2002), the Abstract of which is enclosed herein). As Applicant pointed out in the response to Office Action filed on March 19, 2007, water content in a coating is related to the release rate of a drug, if included in the polymer. Further, water content affects the hydrophilicity or hydrophobicity of a coating.

In sum, Ethicon fails to teach each and every element of claim 1. Claim 1 is therefore patentably allowable over Ethicon under 35 U.S.C. 103(a). Claims 2-4, 6 and 8 depend from claim 1 and are patentably allowable over Ethicon for at least the same reason.

Claim 9 defines a coating for an implantable medical device. The coating includes a polymer and a drug. The polymer has a glass transition temperature of the polymer that allows the morphology of the polymer to change the release rate of the drug when a body temperature of a patient in which the device is implanted rises to a temperature above the patient's normal body temperature. This feature allows a coating including the polymer to change/modulate release rate of drug from the coating when the temperature of a body receiving the coating rises to above the normal body temperature. Ethicon certainly fails to provide or teach a polymer that includes such a glass transition temperature. Therefore, claim 9 is

patentably allowable over Ethicon under 35 U.S.C. 103(a). Claims 10-12, 15, and 16 depend from claim 9 and are patentably allowable over Ethicon for at least the same reason. Further, claim 11 requires the polymer to contain less than about 1 mass % of water. As discussed above, this feature is non-obvious over Ethicon. Therefore, aside from its dependency from claim 9, claim 11 is additionally allowable over Ethicon under 35 U.S.C. 103(a).

The undersigned authorizes the examiner to charge any fees that may be required or credit of any overpayment to be made to Deposit Account No. 07-1850.

CONCLUSION

Withdrawal of the rejection and allowance of the claims are respectfully requested. If the Examiner has any suggestions or amendments to the claims to place the claims in condition for allowance, applicant would prefer a telephone call to the undersigned attorney for approval of an Examiner's amendment. If the Examiner has any questions or concerns, the Examiner is invited to telephone the undersigned attorney at (415) 393-9885.

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Respectfully submitted,



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